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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,603	01/26/2005	Tsunehiro Fukuchi	2005-0024A	3410
513 7590 04/16/2010 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503				
EXAMINER				
CHEN, CATHERYNE				
ART UNIT		PAPER NUMBER		
1655				
NOTIFICATION DATE		DELIVERY MODE		
04/16/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com

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# Office Action Summary

**Application No.**

10/522,603

**Applicant(s)**

FUKUCHI ET AL.

**Examiner**

CATHERYNE CHEN

**Art Unit**

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 8 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 10-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI.08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

### **DETAILED ACTION**

Currently, Claims 8 and 10-12 are pending. Claims 8, 10-11 are examined on the merits. Claims 1-7, 9 are canceled.

### ***Election/Restrictions***

Applicant's election of the species in Claim 8, Kakon-to and Sho-saiko-to, in the reply filed on March 31, 2008 is acknowledged.

Newly submitted claim 12 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The composition can be made in a different manner, such as mixed together in a different manner. For example, alcohol instead of water can be used to make the jelly mixture.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 12 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagasaka et al. (1995, J Med Virol, 46: 28-34) in view of Fujimaki et al. (JP 63239228 A, translation provided), Ninomiya et al. (US 5932235) and San-Ei Chem (JP 54070420 A).

Nagasaka et al. teaches kakkon-to is a traditional herbal medicine for treatment of infectious diseases in China and Japan at a dose corresponding to human use for treating human viral infection (Abstract).

However, Nagasaka et al. does not teach Sho-saiko-to, 0.01-10 w/w% carrageenan, 0.01-10 w/w% carob bean gum, 0.01-10.0% w/w% xanthan gum, and the amount of herbal medicine is 14-30 w/w%.

Fujimaki et al. teaches Shosaikoto is a Chinese medicine that is used as an immunoactivating agent to treat person infected by virus (Abstract). The formulation can

be carried out with conventional procedures by adding suitable excipients, auxiliary components to form powder, granules, tablet, capsules, etc (page 4 of translation).

Ninomiya et al. teaches a jellied medical composition for oral administration which comprises carrageenan and locust bean gum (Claim 1). The carrageenan is in an amount of 0.01-1.0 wt% (Claim 2). The locust bean gum is in an amount of 0.01-1.0 wt% (Claim 3).

San-Ei Chem teaches binder for pharmaceutical preparation with xanthan gum and locust bean (carob bean gum) or carrageenan at 5-10 part of mixture of xanthan gum and locust bean gum (1-10:1-10) of carrageenan (Abstract), which can be converted into 1-10 w/w% xanthan gum and locust bean gum.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition with Kakkon-to and Sho-saiko-to because these medicines are used against viruses. One would have been motivated to make a composition with Kakkon-to and Sho-saiko-to for the expected benefit of treating viral infections. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition with Kakkon-to and Sho-saiko-to in jellied form with xanthan gum, carob bean gum, and carrageenan because Ninomiya et al. and San-Ei Chem teach pharmaceuticals can be formed into jelly by using binders, such as xanthan gum, carob bean gum, and carrageenan. One would have been motivated to

make a composition in jellied form for the expected benefit of creating a medicine that is in a jellied form because jellied form is a conventional way of making a medicine for oral delivery. Absent evidence to the contrary, there would have been a reasonable expectation of success in making the claimed invention from the combined teachings of the cited references.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition with Chinese medicine at 14-30 w/w% of the active agent combination for the following reasons. The references do teach the composition as a jelly for pharmaceutical medicine. San-Ei Chem teaches binder for pharmaceutical preparation with xanthan gum and locust bean (carob bean gum) or carrageenan at 1-10:1-10 (Abstract), which can be converted into 1-10 w/w% xanthan gum and locust bean gum. Ninomiya et al. teaches a jellied medical composition for oral administration which comprises carrageenan and locust bean gum (Claim 1). The carrageenan is in an amount of 0.01-1.0 wt% (Claim 2). The locust bean gum is in an amount of 0.01-1.0 wt% (Claim 3). The amount of Chinese medicine present would have to be adjusted so that a jelly can form. Thus, it would have been obvious to make a composition containing xanthan gum, carob bean gum, carrageenan for use as a jellied medicine. Additionally, the amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, especially within the ranges taught by the reference. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen  
Examiner Art Unit 1655

/Michele Flood/  
Primary Examiner, Art Unit 1655